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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,462	11/08/2001	Laurence S. Sloman	A01P1083	8664
36802	7590	01/13/2005	EXAMINER	
PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			MULLEN, KRISTEN DROESCH	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/053,462

**Applicant(s)**SLOMAN, LAURENCE S. *cn***Examiner**

Kristen Mullen

**Art Unit**

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 9/27/04 (response).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-10,12-15 and 17-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10,12-15 and 17-20 is/are allowed.
- 6) ☒ Claim(s) 1-5,7-9 and 21-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 November 2001 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

Art Unit: 3762

### DETAILED ACTION

1. The indicated allowable subject matter of claims 1-5 is withdrawn in view of the newly discovered reference(s) to Nappholz (5,184,615), and Zhu et al. (6,192,275). Rejections based on the newly cited reference(s) follow.

#### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 7-9, and 21-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the limitation "the evoked response detection algorithm" in lines 10-11. There is insufficient antecedent basis for this limitation in the claim.

Regarding claims 21-24, the evoked response detection algorithm is drawn to non-statutory subject matter since it is "functional descriptive material". There is not a functional interrelationship between the evoked response detection algorithm and other claimed elements of the cardiac pacemaker that permit the functionality to be realized. See MPEP 2106. The examiner suggests amending the claim to read --. . .a computer readable medium encoded with an evoked response detection algorithm . . .--

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-3, and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by

Nappholz et al. (5,184,615).

With respect to claim 1, Nappholz shows a method comprising receiving one or more signals from a sensor; processing the one or more signals to determine a patient state (normal or abnormal cardiac rhythms); and modifying the evoked response detection algorithm based on the detected patient state (predetermined duration of evoked response detection or for as long as the abnormal cardiac condition endures) (Col. 11, lines 10-24).

Regarding claim 21, Nappholz shows an implantable cardiac device comprising a computer readable medium encoded with an evoked response detection algorithm (Fig. 5, step 159), a sensor (25, 35) and a controller (39).

The functional language and introductory statement of intended use in claim 21 have been carefully considered but are not considered to impart any further structural limitations over the prior art.

With respect to claims 2, and 22, Nappholz shows the evoked response detection algorithm is modified by calibrating the algorithm using one or more parameter values

Art Unit: 3762

(predetermined time, or for as long as the abnormal rhythm endures) pertaining to the detected patient state (normal or abnormal rhythm).

Regarding claims 3, and 23, Nappholz shows the evoked response detection algorithm is modified by selecting one or more parameter values (predetermined time, or for as long as the abnormal rhythm endures) based on the detected patient state (normal or abnormal rhythm).

6. Claims 1-5, and 21-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Zhu et al. (6,192,275).

With respect to claim 1 Zhu et al. shows method comprising receiving one or more signals from a sensor; processing the one or more signals to determine a patient state (RMI - respiration modulation index – step 106); and modifying the evoked response detection algorithm (step 110) based on the detected patient state (RMI) (Fig. 7).

Regarding claim 21, Zhu et al. shows an implantable cardiac device comprising a computer readable medium encoded with an evoked response detection algorithm (Fig. 7), a sensor (12) and a controller (28).

The functional language and introductory statement of intended use in claim 21 have been carefully considered but are not considered to impart any further structural limitations over the prior art.

With respect to claims 2, and 22, Zhu et al. shows the evoked response detection algorithm is modified by calibrating the algorithm using one or more parameter values (detection threshold –step 110) pertaining to the detected patient state (normal or abnormal rhythm).

Art Unit: 3762

Regarding claims 3, and 23, Zhu et al. shows the evoked the evoked response detection algorithm is modified by selecting one or more parameter values (detection threshold –step 110) based on the detected patient state (RMI).

With respect to claims 4 and 24, Zhu et al. shows providing a first set of parameter values that correspond with a first patient state (first measured RMI value), providing a second set of parameter values that correspond with a second patient state (second RMI value); and modifying the set of parameter values to the first set or the second set based on the detected patient state (RMI) (Fig. 7).

Regarding claim 5, Zhu et al. shows disabling the automatic capture detection function if the patient state is unstable (fusion or non-capture) (Abs.).

#### ***Allowable Subject Matter***

7. Claims 10, 12-15, and 17-20 are allowed.

8. Claims 7-9 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

#### ***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ekwall (5,683,427) shows measurement of respiration impedance or evoked response is sensed and the stimulation energy is adjusted in accordance with the respiration impedance or evoked response.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

Art Unit: 3762

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
kdm



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